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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 98N-0211]

Removal of Regulations Regarding Certification of Antibiotic Drugs; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) published in the **Federal Register** of May 12, 1998, a direct final rule (63 FR 26066). The direct final rule repealed FDA's regulations governing certification of antibiotic drugs. This document confirms the effective date of the direct final rule.

EFFECTIVE DATE: The effective date of the direct final rule published at 63 FR 26066 is confirmed as September 24, 1998.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: FDA solicited comments concerning the direct final rule for a 75-day period ending July 27, 1998. FDA stated that the effective date of the direct final rule would be on September 24, 1998, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

NCD/

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration Modernization Act, and under authority delegated to the Commissioner of Food and Drugs, notice is given that no objections or requests for a hearing were filed in response to the May 12, 1998, final rule. Accordingly, the amendments issued thereby are effective September 24, 1998.

Dated: September 1, 1998
September 1, 1998

William B. Schultz

William B. Schultz
Deputy Commissioner for Policy

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